

**Baxter**

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November 14, 1997

Docket Number 95S-0158  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Dr. rm. 1-23  
Rockville, MD 20857

**RE: Investigational New Drug Application #6859**

Dear Sir/Madam:

In accordance with 21 CFR §312.54 we are enclosing copies of information concerning research involving an exception to informed consent. This includes information that has been publicly disclosed by the IRBs at Albert Einstein Medical Central (AEMC), Philadelphia, PA; and MetroHealth Medical Center, Cleveland, OH.

Albert Einstein Medical Center

The public disclosure/community consultation information from AEMC includes a press release dated May 5, 1997 (Attachment 1) that was submitted to the local news media, an article which was picked up by the *Olney Times* dated June 26, 1997 (Attachment 2), and an article that was picked by the *Germantown Courier* dated Aug. 27, 1997 (Attachment 3); a flyer which was handed out at the AEMC's "Annual Super Saturday" gathering and at four Einstein/NMA Clinic waiting rooms (Attachment 4). This flyer describes the clinical study and provides the community with a telephone number for questions and comments. Also included are the following: a flyer announcing the July 23, 1997 community meeting (Please note that no one attended this meeting) (Attachment 5); a flyer that was handed out to multiple AEMC departments (e.g., environmental services, maintenance, engineering, laboratory, and nursing departments) announcing a July 30, 1997 meeting (Attachment 6); a copy of the sign-in sheet (Attachment 7) and meeting minutes (Attachments 8) for the July 30, 1997 meeting; and an advertisement announcing the August 12, 1997 employee/community meeting which was placed in the following local papers: *Germantown Courier*, *Philadelphia New Observer Inc.*, *Mt. Airy Times Express*, *Northeast Times Newsweekly*, and the *Olney Times* (Attachment 9); and a copy of the sign-in sheet and meeting minutes (Attachments 10, and 11, respectively) for the August 12, 1997 meeting. Additionally, a letter from Dr. Dalsey (principal investigator) (Attachment 12) was sent with the two flyers described as

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Attachments 4 and 5 to the following people: the mayor, state senators, U.S. Representatives, State Representatives, Council Men and Women, other Healthcare officials, local Fire Chiefs, the Pennsylvania ACEP, a Patient Services group, and 46 civic and religious groups.

AEMC received and documented the following responses: a letter dated July 19, 1997 from State Senator Shirley Kitchen (Attachment 13) expressing questions and concerns regarding this study; the site's response to Shirley Kitchen dated August 13, 1997 (Attachment 14); documented responses to Hotline advertised in press releases and flyers previously described in Attachments 1, 4, and 5; and a response to Baxter from a concerned Philadelphia resident (Attachment 15).

In summary, based on the information received from the clinical site, the investigator and IRB achieved community consultation by sending out a press release to local newspapers that solicited communications from community members by providing information for contacting the principal investigator and the IRB (Attachments 1, 2 and 3); by passing out flyers at AEMC/NMA Clinic waiting rooms and at an annual "Super Saturday" gathering which contained a contact number for questions and concerns; holding three community meetings and mailing the flyer and letters to sixty-six (66) community members consisting of community leaders, elected officials, professional organizations, and churches (Attachments 6, 7 and 8).

#### MetroHealth Medical Center

The public disclosure/community consultation information from MetroHealth Medical Center includes the script used on the site's DCLHb hotline (which was active from July 18, 1997 through September 22, 1997) in English (Attachment 16) and in Spanish (Attachment 17); a transcript from the site's DCLHb hotline requesting further information on DCLHb and the study (Attachment 18); a media release which was picked up August 19, 1997 on the Internet through America On Line (AOL) (Attachment 19); the August 19, 1997 press release (Attachment 20); the summary of the August 19, 1997 WMJI radio interview with Dr. Charles E. Emermán (Attachment 21); the transcript from the August 20, 1997-channel 3 television interview with Dr. William Fallon broadcasted on the 11:00 P.M. local news (Attachment 22); a copy of the letter dated July 11, 1997 (Attachment 23) which was sent to ninety-eight (98) emergency medicine providers in the community (Attachment 24); printed advertisements that appeared in the following local newspapers: *The Plain Dealer* (July 20, 1997), *The Call and Post* (July 24, 1997), and *Neuvos Horizontes* (July 31, 1997-Hispanic newspaper) (Attachment 25); and an article which appeared in the "MetroHealth Update" employee newsletter on September 8, 1997 (Attachment 26).

In summary, based on information received from the clinical site, the investigator and IRB achieved community consultation by printing advertisements in several area newspapers with an interactive 800 number where comments and questions could be addressed, both in English and in Spanish (Attachment 25), and by sending a letter to ninety-eight (98) emergency medicine providers in the community that solicited communications from community members which provided information for contacting the principal investigator and the IRB (Attachments 23 and 24). The investigator

also received feedback and inquiries about the study from the AOL release and the employee newsletter.

The submission has been organized as follows:

**Albert Einstein Medical Center**

- Attachment 1: May 5, 1997 Press Release
- Attachment 2: *Olny News* June 26, 1997 published article
- Attachment 3: *Germantown Courier* August 27, 1997 published article
- Attachment 4: Flyer/handout given at both the "Annual Super Saturday" gathering and four (4) Einstein/NMA clinic waiting rooms
- Attachment 5: Flyer announcing July 23, 1997 community meeting
- Attachment 6: Flyer handed out to multiple departments at the site announcing the July 30, 1997 meeting
- Attachment 7: Sign-in sheet for July 30, 1997 meeting
- Attachment 8: July 30, 1997 Meeting Minutes
- Attachment 9: Advertisement announcing the August 12, 1997 community meeting (published in five (5) local newspapers)
- Attachment 10: August 12, 1997 Meeting Sign-In Sheet
- Attachment 11: August 12, 1997 Meeting Minutes
- Attachment 12: Letter from Dr. Dalsey sent to enclosed address list
- Attachment 13: July 19, 1997 letter from Senator Shirley Kitchen expressing concerns and questions
- Attachment 14: August 13, 1997 response to Senator Shirley Kitchen's letter (Attachment 13)
- Attachment 15: Documented responses to site hotline and Baxter

**MetroHealth Medical Center**

- Attachment 16: Script for DCLHb Hotline (English version)
- Attachment 17: Script for DCLHb Hotline (Spanish version)
- Attachment 18: Transcript from the DCLHb Hotline requesting further information
- Attachment 19: August 19, 1997 media release from America On Line (AOL-Internet)
- Attachment 20: August 19, 1997 press release
- Attachment 21: Summary of August 19, 1997 WMJI radio interview with Dr. Charles E. Emerman

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**MetroHealth Medical Center (Cont'd)**

- Attachment 22: August 20, 1997-channel 3 television interview with Dr. William Fallon
- Attachment 23: July 11, 1997 letter sent to emergency medicine providers in the community
- Attachment 24: Mailing list for July 11, 1997 letter (Attachment 23)
- Attachment 25: Printed Advertisements from 3 local newspapers
- Attachment 26: September 8, 1997 media release

This IND (BBIND #6859) is cross-referenced to Baxter's original BBIND #4426 and subsequent amendments.

If there are any questions concerning this submission, please contact me at (847)270-5313.

Sincerely,



Maulik Nanavaty, Ph.D.  
Director Regulatory Affairs  
Blood Substitutes Program



**DRAFT 5/5/97  
Press Release**

**Contact:** Beth Ann Rachkis  
Senior Communications Specialist  
215-456-6182

**ALBERT EINSTEIN MEDICAL CENTER TO PARTICIPATE IN  
STUDY OF BLOOD SUBSTITUTES**

Albert Einstein Medical Center is one of about 40 sites nationwide chosen to participate in a study of a new blood substitute intended to treat the harmful side effects and possibly prevent death in trauma patients with severe blood loss.

The year-long study, expected to begin early this summer, will involve approximately 20 patients from Albert Einstein Medical Center. Nationwide, approximately 850 patients will participate in the study. Half of the patients involved in the study will receive the blood substitute and half will receive a saline solution. All current standard treatments will be administered to all participants.

The blood substitute, called Diaspirin Cross-Linked Hemoglobin (DCLHb) is a pasteurized human blood solution which carries oxygen. The solution is being tested on trauma patients who arrive at Einstein Medical Center's Emergency Unit in severe shock and who have lost large amounts of blood. Severe blood loss can result in a lack of oxygen to vital tissues resulting in organ damage and death if the patient is not quickly stabilized.

"Use of the solution saves critical time in stabilizing a trauma patient because it does not have to be typed or cross-matched," says William Dalsey, MD, chairman of Einstein's Department of Emergency Medicine.

-more-

The man-made solution is derived from expired human red-blood cells. It undergoes a specialized heating and filtration process which reduces the risk of blood-borne infection. A few *temporary* side effects were noted in patients including yellowing of the skin, a red color in the urine, and changes in some lab test results.

New guidelines adopted by the Food and Drug Administration (FDA) allow for emergency care and research to be conducted without obtaining written consent in studies of emergency therapies in those rare circumstances when consent cannot be provided and the condition requires immediate medical care. These new guidelines are essential to research and life-saving efforts in trauma patients. Once the families are found they will be immediately informed of the study and can decide on continued participation.

“Trauma patients have a 40 percent mortality rate because of the severity of their injuries,” says Mark Kaplan, MD, Einstein trauma. “The first few minutes after a patient reaches the trauma center are critical. We hope that by using the blood substitute we can quickly stabilize the patient in order to perform the emergency surgery that is frequently required in these cases.”

Anyone with questions about Einstein Medical Center’s blood substitute study in trauma cases can contact the Blood Substitute Research Study at 215-456-6854.

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10/06/97

08:01

215 456 8368

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**M**  
MUTUAL  
PRESS CLIPPING SERVICE

JUNE 26, 1997

OLNEY TIMES  
PHILADELPHIA, PA

PKLY - 25.000

*362*  
Albert Einstein Medical Center  
is one of about 40 sites nationwide  
chosen to participate in a study of  
a new blood substitute intended to  
treat the harmful side effects and  
possibly prevent death in trauma  
patients with severe blood loss.

Anyone with questions about  
Einstein Medical Center's blood  
substitute study in trauma cases  
can contact the Blood Substitute  
Research Study at 456-6851.



**GERMANTOWN COURIER**PHILADELPHIA, PA  
WEEKLY 20,000

AUG 27 1997

MUTUAL PRESS CLIPPING SERVICE382 17  
.....**Blood substitute study at Einstein Medical Center**

Albert Einstein Medical Center is one of about 40 sites nationwide participating in a study of a new blood substitute intended to treat the harmful side effects and possibly prevent death in trauma patients with severe blood loss.

The year-long study will involve about 20 Einstein patients. Nationwide, approximately 850 patients will participate. Half will receive the blood substitute and half will receive a saline solution.

The substitute, Diaspirin Cross-Linked Hemoglobin (DCLHb), is a pasteurized human blood solution which carries oxygen. It is being tested on trauma patients who arrive in the Emergency Unit in severe shock and who have lost large amounts of blood, which can result in organ damage and death if not quickly stabilized.

"Use of the solution saves critical time in stabilizing a trauma patient because it does not have to be typed or cross-matched," says William Dalsey, MD, chair of Einstein's Department of Emergency Medicine.

The man-made solution is derived from expired human red-blood cells. It undergoes a heating and filtration process that reduces the risk of blood-borne infection. A

few temporary side effects in some patients include yellowing of the skin, a red color in the urine, and changes in some lab test results.

New guidelines adopted by the Food and Drug Administration (FDA) allow for emergency care and research to be conducted without obtaining written consent in studies of emergency therapies in those rare circumstances when consent cannot be provided and the condition requires immediate medical care. These new guidelines are essential to research and life-saving efforts in trauma patients. Once the families are found they will be immediately informed of the study and can decide on continued participation.

"Trauma patients have a 40 percent mortality rate because of the severity of their injuries," says Mark Kaplan, MD, Einstein trauma surgeon. "The first few minutes after a patient reaches the trauma center are critical. We hope that by using the blood substitute we can quickly stabilize the patient in order to perform the emergency surgery that is frequently required in these cases."

For information on this study call 456-6854.



## Albert Einstein Medical Center to Participate in Study of Blood Substitutes

Albert Einstein Medical Center is one of 40 hospitals nationwide chosen to participate in a study of a new blood substitute to treat the harmful side effects, and possibly prevent death, in trauma patients with severe blood loss. The blood substitute is given in addition to all standard treatments normally given to patients with life-threatening injuries.

The solution is being tested on trauma patients who arrive at Einstein Medical Center's Emergency Unit in severe shock and who have lost large amounts of blood. Half of the patients involved in the study will receive the blood substitute and half will receive a saline solution. The man-made solution is derived from expired human red-blood cells and undergoes a specialized heating and filtration process that reduces the risk of blood-borne infection. A few temporary side effects were noted in some patients including yellowing of the skin, a red color in the urine, and changes in some lab test results.

The year-long study, expected to begin early this summer, will involve approximately 20 patients from Albert Einstein Medical Center. Two other hospitals in Philadelphia will also take part in the study.

New guidelines adopted by the Food and Drug Administration (FDA) allow for emergency care and research to take place without obtaining written consent in those rare cases when the patient is unable to give consent, the family is unavailable and the condition requires immediate medical care. Once the patient is able to give consent or the family is found, they will be immediately informed of the study and can decide on continued participation.

If you have questions or concerns about this study, we urge you to call 215-456-6854 or write us at:

**Blood Substitute Research Study**  
**Department of Emergency Medicine**  
Albert Einstein Medical Center  
5501 Old York Road  
Philadelphia, PA 19141

Albert Einstein  
Medical Center

**Einstein**

Einstein Healthcare Network,  
genius in healthcare



# COMMUNITY MEETING

## Blood Substitute Research Study

Paley 1 Conference Room  
Albert Einstein Medical Center  
5501 Old York Road

Philadelphia, PA 19141

Wednesday, July 23, 1997

6 - 8 pm

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Rx

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**ARE YOU AN EINSTEIN EMPLOYEE?**

**DO YOU LIVE WITHIN 3 MILES OF THE HOSPITAL?**

IF YOU CAN ANSWER "YES" TO BOTH QUESTIONS,  
WE WOULD LIKE TO INVITE YOU TO A **FREE LUNCH!**  
(Hoagies & Soda)

ALL YOU HAVE TO DO IS:

FILL OUT THE TICKET BELOW TO RESERVE YOUR PLACE  
& RETURN IT TO THE EMERGENCY ROOM

COME TO LUNCH AND LISTEN TO A FIFTEEN-MINUTE  
PRESENTATION

THE LUNCH/PRESENTATION WILL BE HELD  
AT 11AM ON WEDNESDAY, JULY 30, 1997  
IN THE PALEY CONFERENCE ROOM

~~cut here~~ ~~cut here~~ ~~cut here~~

I WOULD LIKE TO HAVE A FREE LUNCH AND LISTEN TO THE  
PRESENTATION

My Name Is: \_\_\_\_\_

My Department Is: \_\_\_\_\_

My Home Address Is: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Return this ticket to the Emergency Room by: Monday, July 28th @ 12 noon**



Last Name	First Name	ZipCode	Department	Attended?
Acri	Trisha	19128	Temple Med Student	Trisha Acri
Austin	Nadine	19141	Protective Serv.	<del>Nadine</del>
Booker	Maria D.	19119	ECHO/Stress lab	Maria Booker
Brown	Nate	19141	Maintenance	NATE BROWN
Brown	Mary	19141	Environmental Serv.	Mary Brown
DeJesus	Nelida	19140	Tower 4 North	
Gilbert	James		Maintenance	James Gilbert
Grant	Shever	19141	Environmental Serv.	Shes Grant
Green	Duane M.	19126	Storeroom	Duane Green
Herring	Debbie	19138	Pharmacy	
Hoffmann	Mary Vee	19120	Medical Records	
Hunter	Venessa	19126	Medicine	<del>Venessa</del>
Jackson	Karen A.	19111	Recovery Room	
Jenkins	Ruth	19141	Admission	
McDonald	Laverne	19138	Temp. Secretary	L McDonald
McGlamery	Muriel E.	19144	Neurology	
McMillan	Floretta	19150	Cardiology	F. McMillan
Moore	Audrey	19138	Emergency Med.	Audrey Moore
Richards	Eula	19150	Emergency Med.	
Sistrun	Nikki	19131	Temple Med Student	Nikki Sistrun
Speaker	Alan	19120	Storeroom	Alan Speaker
Tobias	Rebecca	19119	Geriatrics	Rebecca Tobias
Vorn	Sharen	19138	Radiology	Sharen Vorn
Young	Frances	19144	Environmental Serv.	Frances Young

- 1 Ernest Hunter 19138 - ENV. SERV.
- 2 NORMAN Jefferson 19138 - ENV. SERV.
- 3 ~~MARY BRUNN~~
- 4 Dickens, Vern 19140 HEALTH INFO
- 5 Whyler, Ben 19095 HIM
- 6 John Thomas OBGYN



## Employee/Community Meeting of 7-30-97 (11AM)

**Staff present:** William C. Dalsey, MD  
Mark J. Kaplan, MD  
Robert Porter, MD  
Pamela Taggart, RN, PhD  
Amanda Palko (Research Assistant)  
Eileen Brennen, MBA

**Invited Guests present:** see attached sign-in log (flyers were handed out to all attendees)

**Lecture Content:** Dr. Dalsey spoke for approximately 5 minutes on the study guidelines, waiver of consent, and known properties of the study substance (DCLHb). Dr. Kaplan spoke for approximately 5 minutes on the benefits of this new product and how it could possibly impact future trauma care. Dr. Porter spoke for approximately 3 minutes on general aspects of how drugs get approval for use through several phases of testing in animal and human subjects. The floor was opened for questions and a lively discussion followed.

### **Highlights of questions & answers:**

**1 - Will they (the patients) receive blood as well as this new substance?** Yes. All standard of care will be given to patients regardless of whether or not they are in the study. This may include IV fluids, blood, surgery and/or whatever is deemed necessary by the treating physician.

**2 - How can you assure that everyone in the community will know about the study?** Obviously we can't reach every individual, but we will make every attempt to talk to interested parties. For our first community meeting, we mailed notices to local groups. For our second community meeting, we offered this lunch/presentation to employees who live locally. For our third community meeting, we will be advertising in local papers such as the Olney Times. In addition, we encourage you to speak with your neighbors, or members of community groups or churches to which you belong and encourage them to attend our next meeting on August 12 at 6 PM. If you can get a group of 10 or more people together within your community we will be glad to make arrangements to speak with them as well

In addition, there has been press releases at the national level on the basic components of the new substance. It has been announced on local news shows and in the Philadelphia Inquirer, although without mentioning the names of any participating hospitals.

**3 - Is this a blood substitute or a drug?** This is a product made from human blood that has more than one effect. It has the expected beneficial effect of carrying oxygen (that's the function of the hemoglobin naturally occurring in our blood) as well as the unexpected, but beneficial, effect of improving blood pressure and cardiac output. We think this is due to the special processing of the hemoglobin molecule and can only explain it as a drug effect.

**4 - What about people who have religious beliefs against receiving blood?** If we know about this when they come into the ER, we will respect their beliefs by not enrolling them in the study. Unfortunately, the possibility exists that we will not know and they may indeed be placed in the study. It's very similar to the severely injured patients who arrive in severe shock and, not knowing that they are Jehovah's Witnesses for example, we give them blood to treat their condition. But whenever possible, we will respect their wishes when they are known; the protocol is written to insure that we do.

**5 - If my family member is the patient and you ask me about the study and I say no, will you continue to hound me?** Absolutely not. No means no.

**6 - What if the whole community objects to this project?** We will not proceed. However, we want the community to be aware that several things make this project desirable. First of all, we have not had many advancements in the treatment of critical care patients for some time because it has been difficult to get consent from unconscious patients and family are often not present when they are in the Emergency Department. For this reason, the government approved new regulations last year which allowed us to do these types of studies if we follow several strict guidelines: FDA approval of each new study, IRB approval at each institution, an on-going, independent review panel of outside medical & scientific experts, and community notification before each site begins the study.

**7 - Why do the skin/urine change color?** The hemoglobin product is excreted by the kidneys as a red molecule. It also gets trapped temporarily in the skin tissues where it breaks down, causing a yellow color--similar to a bad bruise. It is not an indication of organ failure or toxicity as far as we can tell at this time.

The meeting was adjourned at 11:30, however a few individuals stayed to get further information.

*Pamela Taggart*



## COMMUNITY MEETING STUDY OF BLOOD SUBSTITUTE

Albert Einstein Medical Center's Department of Emergency Medicine invites you to attend a special community meeting to hear about a study of a blood substitute in trauma patients.

The blood substitute will be tested for its effectiveness in treating the harmful side effects and possibly prevent death in trauma patients who are in severe shock and who may have experienced severe blood loss. Many patients eligible for this study may not be able to give consent due to this medical condition, but may be enrolled in the study before consent is obtained. The meeting will be held

Tuesday, August 12, 1997  
at 6pm.  
in the Paley 1 Conference room  
at  
Albert Einstein Medical Center  
5501 Old York Road  
Philadelphia, PA 19141

For more information call 215-456-6854

Albert Einstein  
Medical Center

**Einstein**

Einstein Healthcare Network,  
part of the Einstein

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version #: CM 8-12-97B  
(replaces CM 8-12-97)



**"The toughest job in the world  
isn't being President.  
It's being a parent."**

Every day, I work hard to meet the challenges that come with being President of the United States.

It's a tough job. But there's a tougher job than being the President. It's being a parent.

With drugs, crime and other problems facing our children today, it's tougher than ever to be a good parent.

It's a job that none of us can do alone. That's why 350 wonderful organizations have come together to form the Coalition For America's Children — to help good parents raise good kids.

The Coalition knows hundreds of ways that you can help. Whether you're a young adult who can serve as a role model for troubled teens or a retired person who can supervise an after-school program, the Coalition can get you involved.

To find out what you can do right in your own community, contact the Coalition. They'll help you find a role that fits your schedule and your interests. Whether it's a few afternoons a week or a few hours a month, any time you can give will make a difference.

Thank you.

**COALITION FOR AMERICA'S CHILDREN**

**WE'RE FIGHTING FOR THE CHILDREN**

WHICH SIDE ARE YOU ON?

**WWW.KIDSCAMPAIGNS.ORG • 1-888-544-KIDS**



*Germantown Courier*

6664 GERMANTOWN AVE.  
**344-2426**

local artists, on display through Sept. 14.  
Free. Call 951-2860 for information.

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Albert Einstein  
Medical Center

**Einstein**

Bluebird Healthcare Network,  
giving to healthcare

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### BEAT THE HEAT NIGHT

Unitarian Universalist Church, 6900 Stenton Ave., 7:30 p.m. Singles Scene hosts Beat the Heat — wear your shorts, sneakers and be comfortable. Donation \$7. For information, call 242-9250.

### STORYBOOK STROLL

The Schuykill Center, 8480 Hagy's Mill Rd., 2 p.m. Storytelling, activities and guided walk center around children's book, "Where's My Share," for children 4 - 8 years of age. Free with general admission: \$5; \$3 children under 12. For information, call 482-7300.

### HISTORIC GERMANTOWN TOUR

Germantown Historical Society, 5501 Germantown Ave., 1 - 4 p.m. Tour any three Historic G'town sites for \$10 including Awbury Arboretum, Cliveden, Germantown Historical Society, Grumblethorpe, Maxwell Mansion, RittenhouseTown, Stenton, Uppala and/or Wyck. Call 844-0514 for information.

### DAY

Reed House Gardens, 42 The Strand, New Castle, Delaware, 10 a.m. - 3 p.m., Come watch archaeologists unearth the past and tour Reed House. Call 302-322-8411 for information.

## SUNDAY 10 MOVIES SERIES

Germantown Settlement, 45 W. Maplewood Mall, 1 - 4 p.m. Settlement Div. of Services to children and youth present free movies every Sunday. Refreshments served. Reservations required — call 848-6842.

### MONOTYPES

RittenhouseTown, 206 Lincoln Dr., 10 a.m. - 4 p.m. Experiment in mark making, texture and layering color with printmaker Christine Blair. Fee \$65. For information, call 843-2228 or 438-5711.

(CALENDAR on page 11)

**GREEN AS ACTING CHIEF**—The Philadelphia Housing Authority (PHA) has announced the appointment of Dexter Green as Acting Chief of the 300 member PHA Police Department. Green will be on-loan to PHA from his current job as Commanding Officer of the Philadelphia Police Department's North Division. Green has been a police officer for 25 years.

Temple University Hospital's Department of Obstetrics, Gynecology and Reproductive Sciences is sponsoring a Child Care Open House on Wednesday, August 6th from 11 a.m. to 3 p.m. at the Temple Women's Health Center, Hudson Building, 3425 N. Carlisle St.

## COMMUNITY MEETING STUDY OF BLOOD SUBSTITUTE

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For more information call 215-456-6854

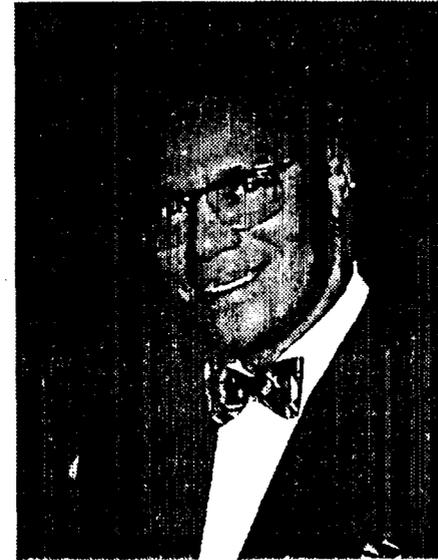
Albert Einstein  
Medical Center

**Einstein**

Einstein Healthcare Network,  
pioneers in healthcare.

# LOUIS FARRAKHA

## SPEAKS!!



A DAY OF ATONEMENT  
A DAY OF ABSENCE

**WEDNESDAY, AUGUST 13, 1997**

FIRST DISTRICT PLAZA  
3801 MARKET STREET  
PHILADELPHIA, PENNSYLVANIA

ADMISSION: \$10.00

DOORS OPEN AT 5:00 PM  
PROGRAM BEGINS AT 6:00 PM

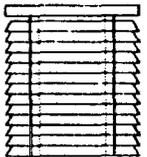
FOR MORE INFORMATION (215) 386-1234

Philadelphia News  
Observer, Inc.

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Only Blinds to Go makes it EASY! Visit our Northeast Philadelphia Superstore  
**2060 COTTMAN AVE.**  
 ... a half mile west of Roosevelt, opposite Toy-R-Us!

**20,000 STYLES** and colors  
 of Blinds & Shades for every budget!  
**AMERICA'S LARGEST CHOICE!**

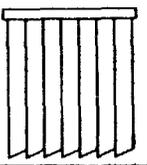


**READY-MADE VENETIAN BLINDS**  
 Premium quality aluminium mini-blinds in 13 great colors and 36 standard sizes. Fade-resistant!

**1339**  
 and UP  
 OUR LOW PRICE!

**So EASY to choose!**

**EXPERT SERVICE!**  
 Nobody knows blinds like we do!  
 We'll make your shopping hassle-free!

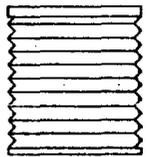


**CUSTOM-MADE VERTICAL BLINDS**  
 Our most popular vinyl vertical blind, with a lifetime guaranteed track!

**2699**  
 and UP  
 OUR LOW PRICE!

**So EASY to shop!**

**FAST 2 DAY DELIVERY!**  
 Why wait? Most custom-made orders are ready to pick up in just 2 days!



**DELUXE FABRIC PLEATED SHADES**  
 Dress your windows in STYLE! Top quality fabric pleated shades, custom-made in your choice of 5 designer colors!

**3099**  
 and UP

**So EASY to save!**

**FACTORY-DIRECT PRICES!**  
 Everything comes from our own factory so we can pass the savings on to you!  
 ...And every product is FULLY GUARANTEED!



**PATIO DOOR SIZE VERTICAL BLIND SPECIAL!**  
 Choice of colors in two styles!

**2999**  
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**COMMUNITY MEETING  
 STUDY OF BLOOD SUBSTITUTE**

Albert Einstein Medical Center's Department of Emergency Medicine invites you to attend a special community meeting to hear about a study of a blood substitute in trauma patients. The blood substitute will be tested for its effectiveness in treating the harmful side effects and possibly prevent death in trauma patients who are in severe shock and who may have experienced severe blood loss. Many patients eligible for this study may not be able to give consent due to this medical condition, but may be enrolled in the study before consent is obtained. The meeting will be held

Tuesday, August 12, 1997  
 at 6pm,  
 in the Paley 1 Conference room  
 at  
 Albert Einstein Medical Center  
 5501 Old York Road  
 Philadelphia, PA 19141

For more information call 215-456-6854

Albert Einstein  
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## FRIDAY 8

END OF DAY DISCUSSION  
 Champagne's, 21 E. Chelton  
 Ave., 10:30 p.m. PA Legislative Black  
 Caucus and NBCSL host open day dis-  
 cussion and socialization after day of meet-  
 ings in memory of Dave Richardson. For in-  
 formation, call 772-1925.

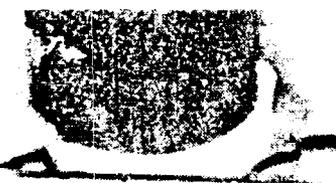
### LATIN FESTIVAL

Robin Hood Dell East, Ridge Ave., 8 p.m.  
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(CALENDAR on page 11)



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**COMMUNITY MEETING STUDY OF BLOOD SUBSTITUTE**

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**Albert Einstein Medical Center - Department of Emergency Medicine  
 Blood Substitute (DCLHb) Study - Community Meeting  
 12 August 1997**

Please print your name	Affiliation (How did you here about this meeting?)
1. J. S. Bland	1. Germantown Courier
2. Jack Conner	2. Greater Olney Com. Council
3. Paula David	3. Germantown Courier
4.	4.
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30.	30.



**Employee/Community Meeting of 8-12-97 (6PM)**

**Staff present:** Robert Porter, MD  
Pamela Taggart, RN, PhD  
Eileen Brennen, MBA

**Invited Guests present:** see attached sign-in log (flyers were handed out to all attendees)

**Lecture Content:** Dr. Porter gave an overview of the current therapies available to trauma patients and the need for new & better treatments. He explained what DCLHb is and why we think it will be high-benefit, low-risk.

**Highlights of questions & answers:**

1. Ms. Bland admitted to being suspicious of the medical community, but asked good questions which we did our best to answer. She said she was aware of the meetings that the "MCP Hospital" had held at the Pickens School. She seemed satisfied with the information we provided.
2. Mr. Connaire thought this was "wonderful." He particularly liked the fact that there is no need to type & crossmatch the patient allowing the DCLHb to be given more quickly. He offered to assist us in placing a press release in the Olney Times, but I said we had already done so. Still, I gave him the name and phone number of our contact in Corporate Marketing & Communication (CM&C).
3. Ms. David came late--Eileen & Pam were cleaning up and Dr. Porter had left. We sat down and explained the study to her. Her attitude was somewhat aggressive. She wanted phone numbers; we gave her the number for the IRB (456-7217), CM&C (456-6182), and Baxter HealthCare (847-270-5300). She wanted to know the demographic data on all studies done to date and for the populations at the hospitals selected for this study (we answered that we did not know and suggested she address those questions to Baxter). She wanted to know if this hospital would make money on this study (we answered that we would only make enough to cover our costs). She asked specific questions about how we had notified our community thus far (which we shared with her) & she felt these were inadequate. I asked her what she would recommend and she gave two suggestions: (1) that we physically go out to the churches and speak at their services, and (2) that we go on talk radio stations that target the black community, such as WHAT and WDAS. She became excited and spoke of a wide range of social issues, including the distrust of the medical community by blacks (attributing the lack of organ donation in this group to their distrust) and the recent tension in Gray's Ferry and how it could happen here when our community finds out what we're trying to do. We reminded her that we have not yet started the study and that we are trying to ensure that the community is aware of the project. She did not persist at this time and said she had to leave.

**Adjourned:** The meeting with #1&2 ended at approximately 6:45 PM; the meeting with #3 ended at approximately 7:25 PM.

*Pamela Taggart, RN*



# Albert Einstein Medical Center

Department of Emergency Medicine  
5501 Old York Road  
Philadelphia, Pennsylvania 19141  
Phone 215-456-6679  
Fax 215-456-8502

July 11, 1997

## To Whom It May Concern:

Albert Einstein Medical Center is one of about 40 sites nationwide chosen to participate in a study of a new blood substitute intended to treat the harmful side effects and possibly prevent death in trauma patients with severe blood loss.

The United States Food and Drug Administration (FDA) has approved the use of "waiver of consent" for this study if certain conditions, including public disclosure and community notification are met. We are notifying your office as part of our plan to remain in compliance with this requirement.

The waiver of consent process will be implemented only when the patient is unable due to his medical condition to legally consent to the study and the next of kin/legal guardian is not present. If these conditions are met, and the patient meets the inclusion criteria for the study we will involve the patient in the study. This does not mean that we will cease our efforts in contacting the family. Once the families are found (or the patient improves to the point where he/she is able to give consent) they will be immediately informed of the study and can decide on continued participation.

The year-long study, expected to begin early this summer, will involve approximately 20 patients from Albert Einstein Medical Center. Nationwide, approximately 850 patients will participate in the study. Half of the patients involved in the study will receive the blood substitute and half will receive a saline solution. All current standard treatments will be administered to all participants.

The blood substitute, Diaspirin Cross-Linked Hemoglobin (DCLHb), is a pasteurized human blood solution which carries oxygen. The solution is being tested on trauma patients who arrive at Einstein Medical Center's Emergency Unit in severe shock and who have lost large amounts of blood. Severe blood loss can result in a lack of oxygen to vital tissues resulting in organ damage and death if the patient is not quickly stabilized. The use of this solution saves critical time in stabilizing a trauma patient because it does not have to be typed or cross-matched.

Blood substitute study  
page 2

The man-made solution is derived from expired human red-blood cells. DCLHb undergoes a specialized heating and filtration process which reduces the risk of blood-borne infection. This blood substitute has been studied in clinical trials for 4 years in over 700 patients. A few *temporary* side effects were noted in patients including yellowing of the skin, red color in the urine, and changes in some lab test results.

Trauma patients have a 40 percent mortality rate because of the severity of their injuries. The first few minutes after a patient reaches the trauma center are critical. We hope that by using the blood substitute we can quickly stabilize the patient in order to perform the emergency surgery that is frequently required in these cases.

If you or your constituents have questions about Albert Einstein Medical Center's blood substitute study in trauma cases, please feel free to contact Pamela Taggart, research coordinator, Department of Emergency Medicine, at 215-456-6854.

Sincerely,



William C. Dalsey, MD  
Chairman  
Department of Emergency Medicine



Mark J. Kaplan, MD  
Director Trauma/Critical Care  
Department of Surgery

**Disclosure/Community Notification  
Mailing List (as of 6/16/97)**

✓ Mayor Edward Rendell  
Room 215  
City Hall  
Philadelphia, PA 19107

/ State Representative  
Dwight Evans  
7174 Ogontz Avenue  
Philadelphia, PA 19138

/ Senator Arlen Specter  
Local Office  
9400 Federal Building  
600 Arch Street  
Philadelphia, PA 19106

) Councilwoman  
Donna Miller  
Room 316  
City Hall  
Philadelphia, PA 19107

| U.S. Representative  
Thomas Foglietta  
10402 Federal Building  
600 Arch Street  
Philadelphia, PA 19106

) Councilwoman  
Marian B. Tascio  
Room 577  
City Hall  
Philadelphia, PA 19107

| U.S. Representative  
Robert A. Borski  
7141 Frankford Avenue  
Philadelphia, PA 19135

/ Councilman at Large  
David Cohen  
Room 588 City Hall  
Philadelphia, PA 19107

| State Senator  
Shirley Kitchen  
119 W. Tabor Road  
Philadelphia, PA 19120

Dr. Joseph A. Zeccardi  
Medical Director  
City of Philadelphia EMS  
Thompson Building, Room 239  
Thomas Jefferson University Hospital  
11<sup>th</sup> and Walnut Streets  
Philadelphia, PA 19107

| State Senator  
Frank Salvatore  
Academy Shopping Center  
3350 Grant Avenue  
Philadelphia, PA 19114

Pennsylvania Trauma Systems  
Foundation  
5070 Ritter Road  
STE 100  
Mechanicsburg, PA 17055-48 79

| State Senator  
Allyson Schwartz  
27 E. Durham Street  
Philadelphia, PA 19119

Chief Larry B. Foster  
Chief of Operations for Fire Department  
Fire Administration Building  
240 Spring Garden Street  
Philadelphia, PA 19123

| State Representative  
Mark B. Cohen  
6001 N. 5<sup>th</sup> Street, 2<sup>nd</sup> Floor  
Philadelphia, PA 19120

Mailed 6/27/97 H. Vaughn

## Mailing List/2

✓ Chief Mike Stanton  
 Administrative Chief for Fire  
 Department  
 Chief of Operations for Fire Department  
 Fire Administration Building  
 240 Spring Garden Street  
 Philadelphia, PA 19123

✓ Captain Daniel Parrish  
 Captain of Operations for Fire  
 Department  
 Chief of Operations for Fire Department  
 Fire Administration Building  
 240 Spring Garden Street  
 Philadelphia, PA 19123

✓ Chief Ralph Halper  
 Director, EMS Regional Office  
 Chief of Operations for Fire Department  
 Fire Administration Building  
 240 Spring Garden Street  
 Philadelphia, PA 19123

David Blum

Exec. Director

✓ Pennsylvania ACEP

777 East Park Drive

P.O. Box 8820

Harrisburg, PA 17105-8820

Gretchen Chadwick,

Patient Representative

Patient Services, HB-5

AEMC

Joyce Douglas  
Health Department Center #9  
131 E. Chelton Avenue  
Philadelphia, PA 19144

Dolores Shine  
Ad Hoc Committee for Logan  
4565 N. Warnock Street  
Philadelphia, PA 19140

Jimmie Robinson  
Citizen of West Logan  
1415 W. Fisher Avenue  
Philadelphia, PA 19141

Marion Johnson  
Concerned Citizens for Olney/Logan  
5024 N. 8th Street  
Philadelphia, PA 19120

Fair Havens Human Support Services  
1250 Wagner Avenue  
P. O. Box 9065  
Philadelphia, PA 19141

Eugene Robinson  
Fern Rock/Ogontz/Belfield Community Development  
Corporation  
201 West Olney Avenue, 4th Floor  
Philadelphia, PA 19123

Ronald Haynes  
Fisher-Windrim Community Development Corp.  
110 Windrim Avenue,  
Philadelphia, PA 19141

Greater Olney Community Council, Inc.  
5212 N. Fairhill Street  
Philadelphia, PA 19120

Phyllis Watts  
Oak Lane Community Action Association  
6521 N. 11th Street  
Philadelphia, PA 19126

Mabel Windham  
Ogontz Area Neighbors Association  
5707 N. 16th Street  
Philadelphia, PA 19141

4-7-97

Gary McNeil  
Penn Area Neighborhood Association  
539 E. Penn Street  
Philadelphia, PA 19141

James M. Shigaki  
Co-Chairpersons  
12th Street & Somerville Avenue Residents  
5342 N. Camac Street  
Philadelphia, PA 19141

Watha Chin  
Cambodian Association of Greater Philadelphia, Inc.  
5412 N. 15th Street  
Philadelphia, PA 19120

Dr. Jin H. Yu  
Korean Community Development Services  
6055 N. 5th Street  
Philadelphia, PA 19120

Joyce Alexander  
Mayor's Office for Community Services,  
Area B, Town Hall  
Germantown & Haines Street  
Philadelphia, PA 19144

Zakiyyah Abdual-Raheem  
East Mount Airy Neighbors  
Mt. Airy Presbyterian Church, Lower Level  
7101 Germantown Avenue  
Philadelphia, PA 19119

Vernon Johnson  
West Mount Airy Neighbors  
Philadelphia, PA

Rev. Rene Perez and The Rev. Wanda Perez  
LaRessurreccion-Lindley United Methodist Church  
5th Street and Fisher Avenue  
Philadelphia, PA 19120

Rev. George F. Bell, Sr.  
Love Missionary Baptist Fellowship  
5801 Ogontz Avenue  
Philadelphia, PA 19141

Rev. Vern M. Joyner  
New Life Seventh Day Adventist Church  
4728 Old York Road  
Philadelphia, PA 19141

Rev. L. V. Johnson  
New Way Missionary Baptist Church  
4845 N. 13th Street  
Philadelphia, PA 19141

Sister Marie McGuigan  
Our Lady of Hope Roman Catholic Church  
5200 N. Broad Street  
Philadelphia, PA 19141

Rev. Samuel Amos Brackeen  
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5801 N. Broad Street  
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Bishop George A. Williams  
Rehobeth Church of God in Christ  
1210 W. Wyoming Avenue  
Philadelphia, PA 19140

Rev. Thomas J. Ritter  
Second Macedonia Baptist Church  
1301 W. Ruscomb Street  
Philadelphia, PA 19141

Rev. David Weeks  
Shalom Baptist Church  
4901 N. 10th Street  
Philadelphia, PA 19141

Bernice Walker  
St. Benedict's Roman Catholic Church  
1940 E. Chelton Avenue  
Philadelphia, PA 19138

Sungsan Presbyterian Church  
901 Spencer Avenue  
Philadelphia, PA 19141

Third Eternal Baptist Church of Germantown  
5364 Chew Avenue  
Philadelphia, PA 19138

Rev. James S. Hall, Jr.  
Triumph Baptist church  
16th & Wingohocking Streets  
Philadelphia, PA 19140

Bishop John E. Williams  
Way of the Cross Church of Christ  
4647 N. Broad Street  
Philadelphia, PA 19141

Rennie Cohen  
Center in the Park  
5818 Germantown Avenue  
Philadelphia, PA 19144

Annette Lutz  
Germantown Settlement-Late Start Satellite  
St. Paul's Church  
4900 N. 5th Street  
Philadelphia, PA 19120

Carolyn Hamphill  
St. Benedict's Senior Center  
St. Benedict's Roman Catholic Church  
1940 E. Chelton Avenue  
Philadelphia, PA 19138

West Oak Lane Senior Center  
7210 Ogontz Avenue  
Philadelphia, PA 19138

Rev. John Green, Jr.  
Christ Baptist Church  
1509 E. Church Lane  
Philadelphia, PA 19141

Florine Moore  
Christ Mission Church of the Apostolic Faith  
Broad Street and Nedro Avenue  
Philadelphia, PA 19141

Rev. John Bilanych, S.T.D., J.U.D.  
Christ the King Ukrainian Catholic Church  
1629 W. Cayuga Street  
Philadelphia, PA 19140

Presbyterian Church of the Redeemer  
Penn  
Chew and Wister Streets  
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Rev. C. L. Pryor  
Corinthian Baptist Church  
6113 N. 21st Street  
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Rev. Harry B. Steward  
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1250 Wagner Avenue  
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Rev. J. N. Lavender  
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Rev. Kermit L. Newkirk, Jr.  
Harold O. Davis Memorial Baptist Church  
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Rev. Edward B. Jones  
Holy Trinity-Bethlehem Presbyterian Church  
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Rev. J. Leroy Saunders  
House of Prayer Episcopal Church  
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Immaculate Conception Roman Catholic Church  
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PHONE (215) 227-6161  
FAX (215) 560-1316

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119 WEST TABOR ROAD  
PHILADELPHIA, PA 19120  
PHONE (215) 457-9033  
FAX (215) 560-3356  
E-MAIL: skitchen@dem.pasen.gov



## Senate of Pennsylvania

July 9, 1997

### COMMITTEES

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STATE GOVERNMENT  
LOCAL GOVERNMENT

Ms. Pamela Taggart  
Research Coordinator  
Albert Einstein Medical Center  
Department of Emergency Medicine  
5501 Old York Road  
Philadelphia, PA 19141

Dear Ms. Taggart:

I am in receipt of the public disclosure/community notification letter dated June 23, 1997 and signed by Drs. William C. Dalsey and Mark J. Kaplan. After reading the information contained therein, I was left with several questions and concerns which I have outlined below.

#### SELECTION CRITERIA

Are the 20 people who will initially be involved in the study current hospital patients or future emergency room trauma patients? If the latter,

- ⇒ What criteria will be used to decide which half receives DCLHb and which half receives the saline solution?
- ⇒ Will those involved be from a select group of people, i.e., poor, Healthy Choices, etc?
- ⇒ If a patient in severe shock and having lost large amounts of blood is included in the study and administered saline solution rather than DCLHb, does the 40% mortality rate increase and what percent are expected not to make it?
- ⇒ Explain how administration of saline solution saves critical time in stabilizing trauma patient and prevents lack of oxygen to vital tissues from resulting in organ damage and/or death.

SIDE EFFECTS:

- ⇒ In what type of lab tests were result changes noted; were these changes positive or negative; were they minor or significant; and what effect does/could these changes have on proper medical treatment including decisions of administration of medication?
- ⇒ How "temporary" are the side effects specified?
- ⇒ Were any NEGATIVE or lasting side effects noted, the possible severity, and method of treatment?

WAIVER OF CONSENT

- ⇒ What, if any, recourse does a patient have who finds him/herself involved in a study against their will or in opposition to religious or other doctrines?
- ⇒ What recourse does patient's family have if patient dies or becomes permanently disabled as a direct result of involuntary participation in this study using waiver of consent? Can/Will Albert Einstein Medical Center be held responsible and liable for damages?
- ⇒ What extra measures will be incorporated to locate the next of kin/legal guardian before inclusion in this study and how diligently will these measures be pursued by hospital staff?

I would be extremely interested and appreciative of a response to my queries as I'm sure many of my constituents will have some of the same concerns. I look forward to hearing from you in the near future.

Sincerely,



Shirley M. Kitchen  
State Senator - 3rd District

SMK:sm



August 13, 1997

Shirley M. Kitchen  
Senate of Pennsylvania  
Senate Box 203003  
The State Capitol  
Harrisburg, PA 17120-3003

Dear Senator Kitchen:

In response to the questions in your letter of July 9, I have prepared the following answers and included documentation for your review. The data is obtained from the Protocol (dated 10-3-97) and the Investigator's Brochure (dated 5-29-97) provided by Baxter Healthcare Corporation.

#### I. Selection Criteria

1. Yes, the 20 people who will be enrolled in the study are future emergency room trauma patients.
  - a. Patients will be randomized by using sealed, sequentially-numbered envelopes. Inside each envelope is the name of the solution that the next patient gets (e.g., the first patient gets whatever is printed inside Envelope #1). These envelopes are prepared in advance by our sponsor, Baxter HealthCare.
  - b. All patients in severe shock will be considered for this study. There are specified criteria which must be met (e.g.,  $\geq 18$  years of age, non-pregnant) including medical criteria (e.g., isolated head injury will exclude a patient from study) and they will be uniformly applied during the course of the study.
  - c & d. Forty percent mortality is the current national average for this group of trauma patients. Saline-treated patients will serve as a placebo control and the mortality rate is expected to remain the same (40%) **since no standard therapy will be withheld from any patients.** Baxter hopes to see as much as a 25% decrease in mortality in DCLHb-treated patients (i.e., mortality would drop from 40% to 30%).

#### II. Side Effects

1. Some laboratory tests have been noted to change with DCLHb use, including proteins and enzymes that could indicate damage to organs such as the pancreas and liver, or to muscles. These include elevated levels of bilirubin, AST, CPK, LD-5, and amylase as well as transient hemoglobinuria. In patients who have received doses of DCLHb greater than 500 ml, jaundice (yellow coloring of the skin) has also been noted.
2. Jaundice starts soon after DCLHb infusion and usually lasts 24-72 hours without the occurrence of any medical problems. In studies to date, the increased laboratory

laboratory values appear after the infusion of DCLHb and most have returned to baseline by Day 7 post-infusion.

3. There have been no trends noted in "lasting side effects." There have been four reports of serious adverse events reported by investigators as being related to the infusion of study product. Two were cases of pancreatitis in surgical patients (one for hip replacement, the other for radical prostatectomy) which both resolved with treatment; one was a case of kidney failure after cardiac bypass surgery which was treated with hemodialysis for two days and then resolved; one case involved death in a stroke patient. It is impossible to say with certainty whether these incidents were caused by the blood substitute or by the patients' underlying medical conditions.

### III. Waiver of Consent

#### 1. Recourse for participation

- a. As soon as the patient regains competency or the next-of-kin is located, they will be informed of the patient's participation in the study and asked to sign a Consent to Continue form. If they refuse, they will no longer participate in the assessments required by the study. You should note however, that the blood substitute will be infused within the first hour of shock and the Consent to Continue will most likely be after-the-fact. There are safety and efficacy assessments which are done for 28 days after receiving the blood substitute and these would not be performed if Consent to Continue was not granted.
- b. We have attempted to address religious beliefs by stating that "known objection to the use of blood or blood products" would exclude a patient from the study.

#### 2. Recourse for death/disability

- a. From the Consent Form: "If I become physically injured as a direct result of participation in this study, the medical care needed to help in my recovery will be provided, at no cost to me, by the sponsor (Baxter Healthcare). No compensation other than free medical care will be provided. I understand that in the event of any injury resulting from my participation in this project, I will be provided with clinically appropriate medical care for that injury within the capabilities of Albert Einstein Medical Center."
- b. However, this drug has been studied in consenting populations prior to the start of this study. These studies include: 24 healthy subjects, 18 hemodialysis patients, 120 hemorrhagic shock patients, 80 orthopedic surgical patients, 60 patients undergoing abdominal aortic repair, 20 patients undergoing "major surgery", 20 "critically ill" patients, 30 "critically ill post-surgical" patients, 80 acute ischemic stroke patients, 80 acute anemia patients, 200 cardiac surgical patient, 26 "high blood loss" surgery patients, 24 "high blood loss" orthopedic surgery patients, and 20 hemodilution patients. **Roughly half of these patients (372 people as of May 29, 1997) have received DCLHb in varying doses.**
- c. The Waiver of Consent for this study has been approved by the U.S. Food & Drug Administration and by the Albert Einstein Medical Center Institutional Review Board, pending community consultation.

3. Because the blood substitute must be given as soon as possible once the patient goes into shock, there will not be time to search for next of kin/legal guardian before initiating the study. However, Research Personnel will begin to look for next of kin as the Trauma Team initiates study participation. The exact steps they will follow are listed in the attached Albert Einstein Medical Center document: Waiver of Consent Guidelines.

We hope this answers your questions and concerns. Thank you for taking the time to familiarize yourself with our proposed study.

Sincerely,

Mark J. Kaplan, MD  
Director of Trauma/Critical Care  
Department of Surgery

Pamela Taggart, RN, PhD  
Clinical Research Coordinator  
Department of Emergency Medicine

## Waiver of Consent Guidelines

### I. Patient/Subject Identification and Legal Representative Notification Algorithm

Many patients who would be candidates for Emergency Medicine Studies may be the victims of multiple trauma and would be incapable of giving informed consent due to the nature of their injuries, pre-existing substance abuse, or medications (e.g., narcotics, anesthesia) received for their injuries. Waiver of consent would be used only in cases where the study subject is not able to give informed consent. When employing the exception from informed consent procedure for participation of a potential subject in a study, the investigator or his/her designees must diligently attempt to (1) establish the identify of the potential subject, and (2) contact the potential study subject's legal representative to obtain informed consent for participation in the study. The procedures employed to establish subject identity should be carried out in parallel with the initial medical treatment of the subject (e.g., stabilization of the subject by hospital personnel, law enforcement officials, paramedical personnel or other qualified individuals at the accident site). **All efforts should be documented in the patient's medical record.**

#### 1. Personal physical search of the subject and his/her possessions.

The personal effects of the subjects should be inspected for clues leading to identification. These effects may include wallets, purses, identification tags, personal effects such as jewelry (engraved watches, wedding bands, bracelets) or miscellaneous effects on the person. The stretcher and blankets upon which the subject was transported should also be examined.

#### 2. Local law enforcement authorities.

Local law enforcement authorities may be called upon to provide assistance to the investigator's institution with respect to the following additional means of subject identification.

- a) If the subject was involved in a vehicular accident, searching the vehicle may provide additional information. Other passengers in the vehicle may be identifiable, which could, if feasible, provide corollary sources of information to identify the subject.
- b) A license plate check of the subject's vehicle through the state motor vehicle agency, if feasible, may yield identity and residence information.

c) Witnesses or passersby at the accident scene may be able to provide information leading to identity of the subject.

3. Fire-rescue/ambulance personnel may have information obtained from the scene where the patient was found. If ambulance personnel have left Einstein, phone calls to the central dispatch can result in their returning your call and answering questions. This works best if implemented *before* a change-of-shift occurs. The ED Medical Clerks can assist you in finding phone numbers for dispatch; please let them know if you are expecting any return calls.

#### B. Contacting the Legal Representative of a Potential Study Subject.

Once the identity of the subject has been established, the investigator must endeavor to contact the legal representative of the subject. It is reasonable to assume that these activities may occur in parallel with the initial stabilization and treatment of the subject by all ordinary and customary medical means. The degree of effort, zeal, and commitment employed in identifying and contacting the legal representative of a subject who is unable to give informed consent should be commensurate with that by which a disinterested observer could reasonably expect an individual truly committed to the goal of finding such a representative.

Specific suggestions for identifying and contacting a subject's next of kin and/or legal representative are as follows:

1. Relevant telephone numbers: at least three calls over sixty minutes to the residence appearing on the patient's driver's license and/or to any identified relatives/legal guardians will be made. Daily or twice daily phone calls after the initial attempts

2. Local law enforcement authorities may, if feasible, urgently visit the subject's or relative's residence in an attempt to establish contact.

## II. Procedures for Obtaining Exception from, and a Waiver of, Informed Consent.

### A. Obtaining informed consent

Upon identification of a potential study subject who is unable to give informed consent by virtue of mental incompetence or impaired mental status, the investigator will, with due diligence, endeavor to contact the subject's legal representative, following the algorithm provided above. The purpose of this contact with the subject's legal representative is to (1) inform the subject's legal

representative of the clinical status of the subject, (2) raise with the subject's legal representative the possibility of participation of the subject in the research study, (3) review the informed consent statement (previously approved by the IRB) with the subject's legal representative, and (4) seek the consent of the subject's legal representative for participation in this study. Informed consent obtained verbally via telephone must be subsequently confirmed in writing.

**B. Waiver of informed consent**

If it is determined that it is not possible to contact the subject's legal representative to obtain informed consent (by use of above algorithm), the investigator may pursue the process for an exception from informed consent. The investigator will document this in the patient's medical record and notify the IRB within five days.

The investigator must continue to make diligent periodic efforts to identify and contact the subject's legal representative to ratify the decision to enroll the subject in the study and to give prospective informed consent for his/her continuing participation in the study. **Documentation of continuing, repeated effort to contact and notify the legal representative of a subject of his/her ongoing and/or past participation in the research study under a waiver of informed consent must be made in the medical record. The investigator will report to the IRB weekly on ongoing attempts to contact the patient's legal representative.**

If the subject regains the ability to give informed consent or initial contact with the subject's legal guardian is made after the patient has been enrolled in the study, the investigator is required to follow the procedures for informed consent and, if agreement is reached, have the subject or his/her legal representative sign a Consent to Continue Form. The person signing the form should be given a copy of both the original Informed Consent and Consent to Continue forms.



# Addendum 1

Response to Hot-line advertised in flyer and press releases:

- 7-10-97: message from George Butts (686-1158), Acting Captain, Philadelphia Fire Department; wanted permission to publish information in his newsletter for paramedics (granted); wanted more info (sent 2 copies of flyer # 5-5-97 to his attention @ Fire Administration Building, 240 Spring Garden Street, Philadelphia, PA 19123-2991)
- 8-4-97: message from Beverly Wheeler (456-6586 @ Einstein); was at Community meeting for Einstein Employees, wanted more written information on the actual blood substitute & how the study will be done (walked over to her office with 2 copies of Consent Form)
- 8-14-97: message from Rob Starkes (951-0330, ext. 126/FAX: 951-0342) from GroundWorks Youth Magazine; left voice mail on his phone on 8-19-97 asking which type of info he was requesting (flyer, letter, consent form); he left voice mail for me later on 8-19-97 and requested a copy of the consent form; on 8-20-97 I faxed a flyer and consent form to him

# Addendum 2

Response to Baxter (?) from “concerned Philadelphia resident”:

8-14-97: message from Baxter that they had received a call from Bernard Jackson (549-2097) offering his help in more community notification; after a few failed attempts, I reached Mr. Jackson on 8-25-97 & he stated that while he was concerned about the “poor turnout” (reported to him by one of the attendees of the 8-12-97 meeting), he was more interested in taking Einstein and/or Baxter as a client since his business is marketing-consulting; we talked for awhile (mostly he talked about the “big companies” and how they do not approach marketing in the best way) and then we said good-bye; he did not request information on the study



## **GREETING**

Thank you for calling the MetroHealth Medical Center trauma research hot line. For information in English press "1". For information in Spanish press "2".

Gracias por llamar a la linea de emergencias para investigacion de traumatismos del MetroHealth Medical Center. Para informacion en ingles, marque "1". Para informacion en espanol, marque "2".

## **INTRODUCTION**

This line is to answer questions about a study we will be conducting at MetroHealth Medical Center. We also ask that you share your views or concerns about this study by leaving a message at the end of this tape. You may also leave a message at any time by pressing "0".

Treating seriously injured trauma patients is one of our specialties at MetroHealth Medical Center. We help many people survive life threatening injuries. In spite of the best medical care available by trauma doctors, some injured patients in severe shock because of bleeding may not survive. It is estimated that with the best care available today, 4 out of every 10 patients with this type of injury will not survive. Finding new ways to save these lives is very important. Studies suggest that a new product, DCLHb may improve the chance of survival after blood loss. The doctors at MetroHealth Medical Center hope that by taking part in this study we may learn how to improve the care of patients with severe blood loss.

To learn about DCLHb press "1". To learn about an exception to informed consent press "2". To learn about the safety, risks and side effects of DCLHb press "3". To learn who may take part in this study press "4" or you may leave a message after the tone.

## **PART ONE**

Baxter Health Care has developed a new blood substitute called Diasprin Cross-Linked Hemoglobin or as we call it DCLHb. It is made from outdated donor blood that can no longer be used for blood transfusions. The blood used to make DCLHb has already been tested and found negative for diseases such as AIDS and Hepatitis. Hemoglobin, the substance in the blood that carries oxygen, is removed from the donor blood. It is then filtered and heat treated to further lower the risk of causing any disease.

DCLHb has shown that it may help patients with severe shock from blood loss because it can carry oxygen to vital organs and tissues and raise blood pressure. DCLHb can save critical moments because it requires no blood typing and can be given immediately after a patient's arrival. Baxter Health Care is now testing DCLHb in many of the countries finest trauma centers, including Metro Health Medical Center, to show if it can help save lives in severe shock from blood loss.

DCLHb is given in addition to all other standard treatments including blood, if necessary. Therefore, there is still a great need for volunteer blood donations.

To return to the main menu press "5" or you may record your message after the tone.

## **PART TWO**

The Federal Food and Drug Administration is allowing Baxter Health Care to do this emergency study under an 'exception from informed consent' because the benefits to those patients who take part in the study are felt to be greater than the risks. DCLHb has the best chance of saving lives if it is given within 30 minutes of the start of shock. Trauma patients in severe shock from bleeding are in desperate need of immediate treatment but may be too ill to give permission to be in this study. Sometimes it may be hard to contact a family member in time to treat the patient with DCLHb. Every effort will be made to get permission before giving DCLHb. If we cannot get permission in time, some patients may receive DCLHb before informed consent occurs. In all cases, permission will be obtained from patients or their families as soon as possible. The patient or family member can then decide whether or not to continue in the study .

To return to the main menu press "5" or you may record your message after the tone.

## **PART THREE**

As with any treatment, it is possible that DCLHb could cause reactions or discomfort. Approximately 350 patients have already received this drug in other studies that have shown the safety of DCLHb. A few temporary side effects have been noted in these studies. These temporary side effects include a harmless yellowing of the skin, a red discoloration of the urine, a change in some lab tests or the inability to do certain tests accurately. Some of the other temporary effects are abnormal kidney function, nausea or vomiting, headache, signs of allergy to DCLHb and stomach, back or muscle pain. DCLHb may also raise blood pressure which may be helpful to patients in shock. The use of DCLHb

could cause reactions that are not yet known. Independent experts will monitor patient safety throughout the trial.

To return to the main menu press "5" or you may record your message after the tone.

#### **PART FOUR**

A total of 850 adult patients may take part in this study in trauma centers throughout the country. Over the next 18 months, approximately 30 critically injured patients will be in this study at MHMC . Pregnant women will not take part in the study. Each person in the study will be assigned to one of two groups by chance. All patients will receive standard trauma care regardless of which group they are in. In addition to standard trauma care, one group will receive DCLHb and the other will receive a saline solution. Patients in both groups will receive all other standard treatment for their injuries, including blood if needed. There will be no extra charges to patients due to the study.

DCLHb may improve the future care and survival of critically injured patients in shock from bleeding. The trauma surgeons and the emergency medicine staff are pleased to be part of the trial of this exciting and promising new product.

To return to the main menu press "5". Please share your comments about this study after the tone. Thank you for your time and input.



PAGE 1/

[INTRODUCTION]

Gracias por llamar a la línea de emergencias para investigación de traumatismos del MetroHealth Medical Center. Para información en inglés, marque "1". Para información en español, marque "2".

Esta línea se ha establecido para responder las preguntas sobre un estudio que se llevará a cabo en el MetroHealth Medical Center. También deseamos brindarle la oportunidad de compartir sus puntos de vista y sus preocupaciones sobre dicho estudio. Usted puede dejar su mensaje en cualquier momento de esta grabación marcando "6".

Una de las especialidades del MetroHealth Medical Center es el tratamiento de pacientes traumáticos gravemente heridos. Ayudamos a muchas personas a superar heridas mortales. Es posible que, a pesar de la excelente atención médica ofrecida por los médicos traumatológicos, algunos heridos con shock grave a causa de masivas hemorragias no sobrevivan. Se estima que, actualmente y con la mejor atención médica disponible, 4 de cada 10 pacientes con este tipo de heridas, no sobreviven. Es muy importante encontrar nuevas maneras de salvar estas vidas. Los estudios demuestran que un nuevo producto, la droga DCLHb, puede mejorar las probabilidades de supervivencia después de la pérdida de sangre. Los médicos del MHMC esperan que, participando de este estudio, les sea posible aprender a mejorar la atención de los pacientes con graves pérdidas de sangre.

Para más información sobre la droga DCLHb, marque "1". Para más información sobre la excepción al consentimiento informado, marque "2". Para más información sobre seguridad, riesgos y efectos secundarios de la droga DCLHb, marque "3". Para más información sobre quiénes pueden participar en este estudio, marque "4" o deje su mensaje después de la señal audible.

[PART ONE]

Baxter Health Care ha desarrollado un nuevo sustituto de la sangre llamado Hemoglobina Diaspirina de Lazos Cruzados o, como lo denominamos nosotros, DCLHb. Este tipo de hemoglobina se fabrica con sangre de donantes vencida que ya no puede ser utilizada en transfusiones. **La sangre que se utiliza para elaborar la droga DCLHb ya ha sido analizada y su resultado es negativo para enfermedades tales como el SIDA y la hepatitis.** La hemoglobina, sustancia de la sangre que transporta el oxígeno, se extrae de la sangre donada. Luego es filtrada y tratada con calor para disminuir aun más el riesgo de causar alguna enfermedad.

El producto DCLHb ha demostrado que puede ayudar a los pacientes en estado de shock severo causado por la pérdida de sangre, ya que puede transportar oxígeno a los órganos vitales y a los tejidos, y elevar la presión sanguínea. Esta droga puede ahorrar instantes de importancia crítica porque no exige un tipo específico de sangre y puede administrarse inmediatamente después del arribo del paciente. Actualmente, Baxter Health Care está probando la droga DCLHb en muchos de los mejores centros de tratamiento traumatológico del país, entre ellos el MetroHealth Medical Center, para demostrar si este componente puede salvar las vidas de los pacientes que han entrado en shock grave debido a una abundante pérdida de sangre.

La DCLHb se administra además de todos los otros tratamientos normalizados, tal como las transfusiones, si éstas fuesen necesarias. Por lo tanto, todavía existe una gran necesidad de contar con donaciones voluntarias de sangre.

PAGE 2/

**Si desea más información sobre la excepción al consentimiento informado, marque "2". Si desea más información sobre seguridad, riesgos y efectos secundarios de la DCLHb, marque "3". Si desea más información sobre quiénes pueden participar en este estudio, marque "4" o deje su mensaje después de la señal audible.**

[PART TWO]

La *Federal Food and Drug Administration* permite a Baxter Health Care llevar a cabo este estudio conforme a una 'excepción al consentimiento informado' **porque se supone que los beneficios para los pacientes que participan en este estudio son mayores que los riesgos.** La droga DCLHb tiene más oportunidad de salvar vidas si se administra en los primeros 30 minutos posteriores al inicio del shock. Los pacientes traumáticos que sufren shock severo debido a una pérdida masiva de sangre tienen la necesidad impostergable de recibir tratamiento de inmediato; sin embargo, es posible que estén demasiado enfermos como para autorizar su participación en este estudio. A veces, es difícil comunicarse a tiempo con un familiar de la víctima para administrarle este producto. Se realizarán todos los esfuerzos necesarios para obtener la autorización antes de administrar la droga DCLHb. Si no puede obtenerse la autorización a tiempo, algunos pacientes pueden recibir la droga DCLHb antes de que se haya obtenido el consentimiento informado. En todos los casos, se obtendrá la autorización de los pacientes o de sus familiares tan pronto como sea posible. El paciente o un familiar del paciente pueden decidir si desean o no continuar participando en el estudio.

Si desea más información sobre la droga DCLHb, marque "1". Si desea más información sobre seguridad, riesgos y efectos secundarios de la droga DCLHb,

marque "3". Si desea más información sobre quiénes pueden participar en este estudio, marque "4" o deje su mensaje después de la señal audible.

[PART THREE]

Tal como en cualquier otro tratamiento, es posible que la administración de la droga DCLHb provoque ciertas reacciones e incomodidad al paciente.

Alrededor de 350 pacientes ya recibieron esta droga durante el curso de otros estudios, lo cual demuestra la seguridad de la misma. En este tipo de estudios, es posible observar algunos efectos secundarios temporarios. Estos efectos secundarios temporarios pueden incluir una coloración amarillenta de la piel inofensiva, una coloración rojiza de la orina, cambios en algunos análisis de laboratorio o la imposibilidad de realizar con precisión determinados análisis. Otros efectos secundarios pueden incluir funcionamiento renal anormal, náuseas o vómitos, dolor de cabeza, síntomas de alergia a la droga DCLHb y dolor estomacal, muscular o de espalda. Es posible que la administración de esta droga aumente la presión sanguínea, lo cual puede ser beneficioso para los pacientes en estado de shock. El uso de la droga DCLHb puede provocar reacciones que todavía se desconocen. Durante todo el estudio, la supervisión de la seguridad de los pacientes estará a cargo de expertos independientes.

Si desea más información sobre la droga DCLHb, marque "1". Si desea más información sobre la excepción al consentimiento informado, marque "2". Si desea más información sobre quiénes pueden participar en este estudio, marque "4" o deje su mensaje después de la señal audible.

[PART FOUR]

Un total de 850 pacientes adultos pueden participar en este estudio en los centros de traumatología de todo el país.

PAGE 3/

Durante los próximos 18 meses, alrededor de 30 pacientes gravemente heridos participarán en este estudio en el MHMC. Las mujeres embarazadas no participan en este estudio. Cada persona que participe en el estudio será asignada al azar a uno de dos grupos. Todos los pacientes recibirán la atención traumatológica normalizada, sin consideración del grupo al que pertenezcan. Además de la atención traumatológica normalizada, un grupo recibirá la droga DCLHb y el otro, una solución salina. Los pacientes de ambos grupos recibirán todos los otros tratamientos normalizados que requieran sus heridas, tal como transfusiones si éstas fuesen necesarias. No habrá cargos adicionales para los pacientes que participen en el estudio.

La droga DCLHb puede mejorar la atención y la supervivencia futura de los pacientes gravemente heridos en estado de shock como consecuencia de una pérdida masiva de sangre. Tanto los cirujanos traumatológicos como el

personal médico de emergencia se sienten complacidos de participar en el estudio de un producto nuevo tan promisorio.

**Si desea más información sobre la droga DCLHb, marque "1". Si desea más información sobre la excepción al consentimiento informado, marque "2". Si desea más información sobre seguridad, riesgos y efectos secundarios del producto DCLHb, marque "3". Por favor, deje sus comentarios sobre el estudio después de la señal audible. Gracias por su tiempo y sus opiniones.**



MetroHealth Medical Center  
2500 MetroHealth Drive, Cleveland, Ohio 44109-1998

216 398-6000

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Transcript of DCLHb hot line messages

August 26, 1997 1:29 PM

Dr. Joseph Layon, MD, SACP, would like to have further written information on DCLHb the product and the study. You can reach him at 352-395-0049,

Department of Anesthesiology  
Division of Emergency Medicine  
Box 100392  
Gainesville, Florida 32610  
The Shens Hospital at the University of Florida





rita cydulka, 04:57 PM 8/26/97, Fwd: Preventing Trauma Deaths

X-Sender: rcydulka@mhnet.mhmc.org  
To: ltrexler,cemerman  
From: rita cydulka <rcydulka@metrohealth.org>  
Subject: Fwd: Preventing Trauma Deaths Is Target Of MetroHealth Study

>Date: Sat, 23 Aug 1997 12:19:55 -0400 (EDT)  
>From: Rcydulka@aol.com  
>To: rcydulka@metrohealth.org  
>Subject: Fwd: Preventing Trauma Deaths Is Target Of MetroHealth Study

>-----  
>Forwarded message:  
>Subj: Fwd: Preventing Trauma Deaths Is Target Of MetroHealth Study  
>Date: 97-08-20 12:21:54 EDT  
>From: AES6  
>To: Rcydulka

>Dear Rita: Once again you are in the national news ....

>Al

>-----  
>Forwarded message:  
>Subj: Preventing Trauma Deaths Is Target Of MetroHealth Study  
>Date: 97-08-19 21:24:35 EDT  
>From: AOL News

> CLEVELAND, Aug. 19 /PRNewswire/ MetroHealth Medical Center is one of 35

>hospitals across the country which is testing a potentially live-saving  
>treatment for patients suffering from severe traumatic injuries.  
Known as

>the  
>DCLHb Trauma Study, the study focuses on patients with life-threatening blood  
>loss through the administering of an oxygen-rich blood substitute, along  
>with standard emergency treatment.

> The oxygen-carrying blood substitute has significant application in

>trauma  
>situations where large amounts of blood loss may result in lack of oxygen to  
>vital tissues. Patients can go into shock, which can lead to multiple organ  
>failure several days or weeks after the initial trauma. The new blood  
>solution has the ability not only to carry blood to these tissues,

Printed for Lee Trexler <ltrexler@metrohealth.org>

1

rita cydulka, 04:57 PM 8/26/97, Fwd: Preventing Trauma Deaths

but seems  
>to increase blood flow to vital organs when a patient is in shock.  
> Half of the approximately 30 patients whom MetroHealth will  
study  
>will  
>receive the blood substitute in the Emergency Department; the other  
half  
>will  
>receive a placebo, saline solution, in addition to the standard  
emergency  
>care.  
> More than 150,000 people die annually from trauma-related  
injuries,  
>making  
>this the number one cause of death for Americans under the age of 45.  
> Another  
>two million people are severely injured every year in this country.  
With all  
>traumas, time is of paramount importance in treating the patient.  
> "It is critical in trauma situations that the  
oxygen-carrying  
>solution be  
>given within the first hour of the patient's arrival at the  
hospital," said  
>Rita K. Cydulka, director of MetroHealth's Emergency Medicine  
Residency  
>Program and principal investigator for the DCLHb study. This is now  
>possible,  
>even without family consent, because of recently adopted guidelines  
by the  
>U.S. Food and Drug Administration and the Office of Protection of  
Patient  
>Rights which waive consent in studies of emergency therapies.  
> "More than 700 patients across the country with other  
illnesses  
>have  
>participated in hemoglobin studies with encouraging results," said  
Dr.  
>Cydulka. "We hope for similar results from DCLHb."  
> The DCLHb product is manufactured by Baxter Healthcare  
Corporation  
>and  
>the study is supervised by the FDA. For more information on the  
study, call  
>216-778-2131.  
> CO: The MetroHealth System  
> ST: Ohio  
> IN: HEA  
> SU:

Printed for Lee Trexler <ltrexler@metrohealth.org>

2

rita cydulka, 04:57 PM 8/26/97, Fwd: Preventing Trauma Deaths

>  
>To edit your profile, go to keyword NewsProfiles.  
>For all of today's news, go to keyword News.

>  
>  
Rita K. Cydulka, M.D.  
Residency Director,  
Emergency Medicine  
MetroHealth Medical Center  
Case Western Reserve University School of Medicine  
Cleveland, Ohio  
ph:216-778-5088  
fax: 216-778-5349  
e-mail address: RICYDULKA@METROHEALTH.ORG

Printed for Lee Trexler <ltrexler@metrohealth.org>

3



Tuesday August 19 12:45 PM EDT

Company Press Release  
Source: The MetroHealth System

*Cleveland Metro  
Medical Center*

### **Preventing Trauma Deaths Is Target Of MetroHealth Study**

CLEVELAND, Aug. 19 /PRNewswire/ MetroHealth Medical Center is one of 35 hospitals across the country which is testing a potentially life-saving treatment for patients suffering from severe traumatic injuries. Known as the DCLHb Trauma Study, the study focuses on patients with life-threatening blood loss through the administering of an oxygen-rich blood substitute, along with standard emergency treatment.

The oxygen-carrying blood substitute has significant application in trauma situations where large amounts of blood loss may result in lack of oxygen to vital tissues. Patients can go into shock, which can lead to multiple organ failure several days or weeks after the initial trauma. The new blood solution has the ability not only to carry blood to these tissues, but seems to increase blood flow to vital organs when a patient is in shock.

Half of the approximately 30 patients whom MetroHealth will study will receive the blood substitute in the Emergency Department; the other half will receive a placebo, saline solution, in addition to the standard emergency care.

More than 150,000 people die annually from trauma-related injuries, making this the number one cause of death for Americans under the age of 45. Another two million people are severely injured every year in this country. With all traumas, time is of paramount importance in treating the patient.

"It is critical in trauma situations that the oxygen-carrying solution be given within the first hour of the patient's arrival at the hospital," said Rita K. Cydulka, director of MetroHealth's Emergency Medicine Residency Program and principal investigator for the DCLHb study. This is now possible, even without family consent, because of recently adopted guidelines by the U.S. Food and Drug Administration and the Office of Protection of Patient Rights which waive consent in studies of emergency therapies.

"More than 700 patients across the country with other illnesses have participated in hemoglobin studies with encouraging results," said Dr. Cydulka. "We hope for similar results from DCLHb."

The DCLHb product is manufactured by Baxter Healthcare Corporation and the study is supervised by the FDA. For more information on the study, call 216-778-2131.

SOURCE: The MetroHealth System



October 10, 1997

Raymond A. Knight, CRA  
Baxter Healthcare Corporation  
Blood Substitutes  
Route 120 & Wilson Road WG2-3S  
Round Lake, Illinois 60073

Dear Mr. Knight,

Charles E. Emerman, MD, Chairman of the Department of Emergency Medicine at MetroHealth Medical Center conducted an interview with the WMJI-FM radio station on August 19, 1997. Dr. Cydulka, the site principle investigator, was out of town on that date. Dr. Emerman recalled to me that the interview consisted of brief questions and answers about the study, such as:

- why the study is important
- how it will help trauma patients in severe hemorrhagic shock
- the general nature of the study
- reasons we put out announcements about the study

I hope this provides the information you need regarding the interview. Please let me know if any other information is required.

Sincerely,



Amy McPherson, RN  
Emergency Medicine Research Assistant

AMC

cc: ClinTrials Research, Inc.



## Metrohealth System Video

Date: Unknown

### Newsroom Scene:

Newsman (Name not provided): "A blood substitute could be pumped into your veins if you need it. Metrohealth Medical Center is one of 35 hospitals nationwide that will start administering an oxygen rich blood substitute to patients with life-threatening blood loss. It could increase blood flow to vital organs when a patient is in shock."

### Hospital Scene:

Dr. William Fallon, Jr., Trauma Care Metrohealth: "...somebody is bleeding or has actually lost blood and you can document that, or that their vital signs are unstable enough so we would call it at the shock state, those are the people we would target for this study."

Newsman narrates: "Dr. Fallon said the experiment known as OCLHb trauma study will begin testing very very soon."

NOTE: Newsman spelled out O-C-L-H-B, not DCLHb.



July 11, 1997

Dear Emergency Medicine Provider:

MetroHealth Medical Center (MHMC) has been selected as one of 40 major trauma centers to participate in the evaluation of a new blood substitute for trauma patients suffering from severe blood loss. As you know, patients with Class 3 or Class 4 hemorrhagic shock have an expected mortality rate of at least 40%. Clearly the development of improved therapies for this condition is vital.

A new blood substitute manufactured by Baxter Health Care, Inc, Diasprin Cross-Linked Hemoglobin (DCLHb), has potential to improve survival in hemorrhagic shock. The safety of DCLHb has been established through clinical trials throughout the US. Some of the important DCLHb product properties include:

- Increase in Mean Arterial Pressure
- Restoration of Base Deficit
- Restoration of Lactate Levels
- Restoration of Subcutaneous PO<sub>2</sub>
- Restoration of Mucosal PO<sub>2</sub>
- Reduction of Bacterial Translocation

DCLHb has many other beneficial properties. It is a purified hemoglobin solution manufactured from units of outdated human donor blood. The manufacturing process includes several steps which effectively reduce the risk of virus transmission to that of other heat treated biologic solutions, such as albumin. In addition, DCLHb requires no blood typing and can be stored in the emergency department, thereby saving precious moments in the treatment of this life threatening condition.

Approximately 850 patients will be enrolled throughout the country in this important trial. Each patient will be randomly assigned into one of two patient groups. One group of patients will serve as a control, the other group will receive DCLHb. Patients in BOTH groups will receive ALL STANDARD THERAPIES for their condition, including blood transfusions, if appropriate. Patients will incur no additional expenses due to their participation in this study.

The conduction of this trial is possible in part because of new FDA regulations governing an exception from informed consent. Trauma patients experiencing hemorrhagic shock may not be able to provide informed consent to participate in a drug trial, yet are in critical need of immediate treatment. The FDA has granted the exception from informed consent for this trial because the benefits of participation greatly outweigh the risks. Every effort will be made to obtain consent from patients or their family members before study enrollment. However, in some cases it will not be possible to obtain consent within the time frame for treatment necessitated by the critical nature of patient condition. In these cases, informed consent will be obtained from all participants or their

families as soon as possible. The patient or family member can decline further participation at any time.

As with any treatment, it is possible that DCLHb could cause reactions or discomfort. Approximately 350 patients have already received this drug in other studies that have shown the safety of DCLHb. A few temporary side effects have been noted in these studies including:

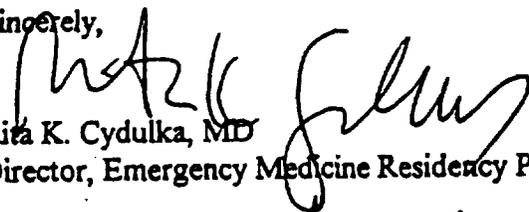
- headache, muscle, back or abdominal pain
- general weakness
- a red discoloration in urine (not true hematuria)
- nausea/vomiting
- a temporary inability to do some tests accurately
- a temporary elevation of certain lab test results
- allergic reactions
- abnormal kidney function
- temporary jaundice
- temporary rise in blood pressure

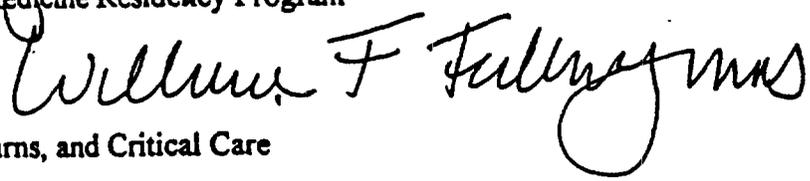
The use of DCLHb could cause reactions that are not currently known. Because DCLHb is an investigational solution and the effects in pregnancy have not been determined, pregnant women will not participate in the study.

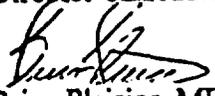
The FDA requires public notification for studies which may be conducted under exception from informed consent. This letter is being sent to area emergency departments to inform area health care providers involved in the care of trauma patients of the study, as well as to satisfy, in part, the FDA requirements.

We at MetroHealth Medical Center recognize importance of improvements in trauma care. We are excited about the potential DCLHb holds for the future. Medical research may provide new, improved methods for health care providers to save the lives of critically injured trauma patients.

Sincerely,

  
Rita K. Cydulka, MD  
Director, Emergency Medicine Residency Program

  
William Fallon, MD  
Director of Trauma, Burns, and Critical Care

  
Brian Plaisier, MD  
Director of Trauma



**DCLHb MAILING LIST OF AREA EMERGENCY DEPARTMENT DIRECTORS**

**Akron City Hospital-Akron, Ohio**

**Akron General Medical Center -Akron, Ohio**

**Allen Memorial Hospital-Oberlin, Ohio**

**Alliance City Hospital-Alliance, Ohio**

**Amherst Hospital-Amerherst, Ohio**

**Andover Medical Center Warren-Andover, Ohio**

**Ashland Samaritan Hospital-Ashland, Ohio**

**Ashtabula General Medical Center-Ashtabula, Ohio**

**Aultman Hospital-Canton, Ohio**

**Barberton Citizens Hospital- Barberton, Ohio**

**Bellvue Hospital-Bellvue, Ohio**

**Blanchard Valley Hospital- Findlay, Ohio**

**Brown Memorial Hospital- Conneaut, Ohio**

**Bucyrus Community Hospital-Bucyrus, Ohio**

**Chagrin Valley Medical Center-Chagrin, Ohio**

**Community Hospital Bedford-Bedford, Ohio**

**Community Medcenter Hospital- Marion, Ohio**

**Coshocton County Memorial Hospital-Coshocton, Ohio**

**Crestline Memorial Hospital- Crestline, Ohio**

**Cuyahoga Falls Hospital-Cuyahoga Falls, Ohio**

**Deaconess Hospital-Cleveland, Ohio**

**Defiance Hospital-Defiance, Ohio**

Doctors' Hospital Stark County-Massilon, Ohio  
Dunlap Memorial Hospital-Orrville, Ohio  
East Liverpool City Hospital-East Liverpool, Ohio  
East Ohio Regional Hospital-Martin's Ferry, Ohio  
Elyria Memorial Hospital-Elyria, Ohio  
Fairview General Hospital- Cleveland, Ohio  
Firelands Community Hospital-Sandusky, Ohio  
Fischer-Titus Memorial Hospital-Norwalk, Ohio  
Fostoria City Hospital-Fostoria, Ohio  
Freemont Hospital-Freemont, Ohio  
Galion Community Hospital-Galion, Ohio  
Geauga Community Hospital-Chardon, Ohio  
Grace Hospital-Cleveland, Ohio  
Gurnsey Memorial Hospital-Cambridge, Ohio  
Harrison Community Hospital-Cadiz, Ohio  
Hillside Hospital- Warren, Ohio  
Joel Pomerene Hospital-Millersburg, Ohio  
Kaiser Foundation Hospital-Parma, Ohio  
Kettering Hospital-Loudonville, Ohio  
Knox Community Hospital-Mt. Vernon, Ohio  
Lake County East-Painsville, Ohio  
Lake Count West-Willoughby, Ohio  
Lakewood Hospital-Lakewood, Ohio

Licking Memorial Hospital- Newark, Ohio

Lima Memorial Hospital-Lima, Ohio

Lodi Community Hospital-Lodi, Ohio

Lorain Community/St. Joseph Hospital(East and West Campus)-Lorain, Ohio

Lutheran Medical Center-Cleveland, Ohio

Meridia Ambulatory Care-Sagamore Hills, Ohio

MacGruder Memorial Hospital-Port Clinton, Ohio

Mansfield General-Mansfield, Ohio

Marietta Memorial Hospital-Marietta, Ohio

Marion General Hospital-Marion, Ohio

Marymount Hospital-Garfield, Ohio

Massillon Community Hospital-Massillon, Ohio

Medical Center South-Broadview Heights, Ohio

Medical College Of Ohio-Toledo, Ohio

Medina General Hospital-Medina, Ohio

Memorial Hospital of Geneva-Geneva, Ohio

Mercy Hospital-Tiffin, Ohio

Meridia Euclid-Euclid, Ohio

Meridia Hillcrest-Mayfield Hts, Ohio

Meridia Huron-Cleveland, Ohio

Meridia Southpoint-Warrensville Hts, Ohio

Morrow County Hospital-Mt Gilead, Ohio

Mt. Sinai Medical Center-Cleveland, Ohio

**Parma Community General Hospital-Parma, Ohio**

**People's Hospital-Mansfield, Ohio**

**Potters Medical Center-East Liverpool, Ohio**

**Providence Hospital- Sandusky, Ohio**

**Richmond Hospital- Mansfield, Ohio**

**Richmond Hts. General Hospital-Richmond Hts., Ohio**

**Robinson Memorial Hospital-Ravenna, Ohio**

**Salem Community Hospital-Salem, Ohio**

**Shelby Memorial Hospital-Shelby, Ohio**

**Southwest Health Center-Middleburg Hts, Ohio**

**St. Alexis Hospital-Cleveland, Ohio**

**St. Elizabeth Medical Center-Youngstown, Ohio**

**St. John Westshore-Westlake, Ohio**

**St. John Medical Center-Steubenville, Ohio**

**St. Lukes Hospital-Cleveland, Ohio**

**St. Lukes Solon-Solon, Ohio**

**St. Thomas Hospital-Akron, Ohio**

**St. Vincent Charity Hospital-Cleveland, Ohio**

**St. Vincent Medical Center-Toledo, Ohio**

**Tiffin Mercy Medical Center-Tiffin, Ohio**

**Columbia Mercy Medical Center-Canton, Ohio**

**Trumbull Memorial Hospital-Warren, Ohio**

**Twin City Dennison-Dennison, Ohio**

Union Dover Hospital-Dover, Ohio

VA Medical Center-Cleveland, Ohio

Wadsworth-Rittman Hospital-Wadsworth, Ohio

St. Joseph Health Center-Warren, Ohio

Western Reserve North and South-Youngstown, Ohio

Willard Mercy Hospital-Willard, Ohio

Wooster Community Hospital-Wooster, Ohio



# Un mensaje importante de los cirujanos de trauma y el personal de emergencia médica en el MetroHealth Medical Center



*MetroHealth Medical Center es uno de 40 centros de traumas en los Estados Unidos que estudia un nuevo tratamiento que tiene el potencial de salvar las vidas de pacientes de trauma severamente golpeados que estén en estado de conmoción debido a la pérdida de sangre.*

El tratamiento es un agente de carga oxígeno conocido como "Diaspirin Cross-Linked Hemogloblin (DCLHb)," derivado de la sangre humana. "DCLHb" ha sido probado en prácticas clínicas a través del país con más de 350 pacientes, y su seguridad está bien documentada. Ha sido demostrado que aumenta la presión sanguínea y puede bajar la necesidad de transfusiones de sangre.

Aproximadamente de 20-30 pacientes participarán en este estudio en MetroHealth. Estos pacientes serán hombres y mujeres de 18 años de edad o mayores que estén sufriendo de una pérdida de sangre seria y que estén en un gran riesgo de morir. Los pacientes estudiado pueden recibir el agente de hemoglobina en adición a los tratamientos.

El estudio es hecho posible en parte por las nuevas líneas de guía de la "Food and Drug Administration." Las líneas de guía permiten a los médicos, bajo control riguroso, el administrar nuevos tratamientos con potenciales de salvar vidas a pacientes demasiado enfermos para dar su consentimiento. Bajo las líneas de guía, pacientes con condiciones que amenacen la vida y que estén indisponibles para firmar un consentimiento, o que no tengan un miembro de la familia que pueda firmar por ellos, todavía pueden estar disponibles para recibir terapias de pruebas prometedoras en adición a los tratamientos incluyendo transfusiones de sangre.

La participación en este estudio es confidencial. Todo esfuerzo de obtener consentimiento de un miembro de la familia o representante legal autorizado será hecho. Si un consentimiento informado para participar en este estudio no puede ser obtenido durante el periodo de tiempo crítico de 30 minutos después que el paciente sea admitido al hospital, el paciente puede ser entrado en el estudio bajo la "excepción del consentimiento informado" autorizado por la "FDA." Consentimiento para continuar la participación en el estudio será obtenido del paciente o un miembro de la familia tan pronto sea posible.

Los golpes traumáticos es la causa principal de muerte dentro de Americanos bajo la edad de 45, y afecta a casi 2 millones de personas cada año. Los resultados de este estudio ayudarán al conocimiento avanzado acerca del tratamiento de golpes traumáticos severos.

Una línea especial ha sido establecida al (216) 778-2131 para responder a preguntas acerca del estudio.

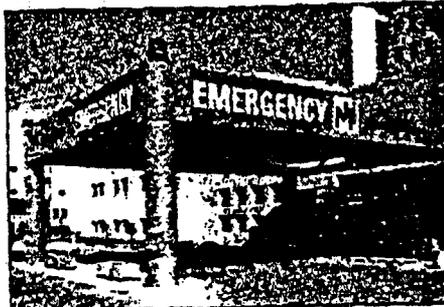


## MetroHealth Medical Center

2500 MetroHealth Drive, Cleveland, Ohio 44109-1998

THE PLAIN DEALER • SUNDAY, JULY 20, 1997

## **A**n important message from the trauma surgeons and emergency medical staff at MetroHealth Medical Center



*MetroHealth Medical Center is one of 40 trauma centers in the United States to study a new treatment that has the potential to save the lives of severely injured trauma patients who are in shock due to blood loss.*

The treatment is an oxygen-carrying agent known as Diaspirin Cross-Linked Hemoglobin (DCLHb), derived from human blood. DCLHb has been tested in clinical trials across the country with more than 350 patients, and its safety is well documented. It has been shown to increase blood pressure and may decrease the need for blood transfusions.

Approximately 20-30 patients will be enrolled in this study at MetroHealth. These patients will be men and women 18 years of age or older who are suffering from serious blood loss and are at the greatest risk of dying. Study patients may receive the hemoglobin agent in addition to standard treatments, including blood transfusions.

The study is made possible in part by new guidelines from the Food and Drug Administration. The guidelines allow physicians, under rigorous control, to administer new, potentially life-saving treatment to patients too ill to give their consent. Under the guidelines, patients with life-threatening conditions who are unable to sign a consent, or who do not have a family member who can sign for them, still may be eligible to receive promising trial therapies in addition to standard treatments:

Participation in this study is confidential. Every effort to obtain consent from a family member or legally authorized representative will be made. If informed consent to participate in this study cannot be obtained during the 30-minute critical time period after a patient is admitted to the hospital, the patient may be entered into the study under the "exception from informed consent" authorized by the FDA. Consent to continue participation in the study will be obtained from the patient or family member as soon as possible.

Traumatic injury is the leading cause of death among Americans under age 45, and affects nearly 2 million people every year. The results of this study will help advance knowledge about the treatment of severe traumatic injuries.

A hotline has been established at (216) 778-2131 to respond to questions about this study.



### **MetroHealth Medical Center**

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A potential life-saving treatment for patients inflicted with severe traumatic injuries is being tested in the medical center's Emergency Department. MetroHealth is one of 35 hospitals in the country conducting the DCLHb Trauma Study, focusing on patients with life-threatening blood loss by administering an oxygen-rich blood substitute along with standard emergency treatment.

In trauma situations where there is acute blood loss, the oxygen-carrying blood substitute has significant application. This new blood solution has the ability not only to carry blood to vital tissues, but also seems to increase blood flow to vital organs when a patient is in shock. Half of nearly 30 patients who will be involved in the study at MetroHealth will receive the blood substitute; the others will receive a placebo, saline solution in addition to the standard emergency care.

It is critical in trauma situations that the oxygen-carrying solution be given within the first hour of the patient's arrival at the hospital," says Rita Cydulka, director of the Emergency Medicine Residency Program and principal investigator for the DCLHb study. "More than 700 patients across the country with other illnesses have participated in hemoglobin studies with encouraging results. We hope for similar results from DCLHb."

Studies such as this one are now possible because of recently adopted guidelines by the U.S. Food and Drug Administration and the Office of Protection of Patient Rights which waive consent in studies of emergency therapies. The study is being supervised by the FDA.

#### More MetroHealth Distinctions

In last week's edition of *Update* we published some of the notable distinctions that set MetroHealth apart from other health care organizations. Today, we continue that list of distinctions that help shape The MetroHealth System.

- **Accreditations** - MetroHealth is Accredited by the Joint Commission on Accreditation of Health Care Organizations and by the Committee on Accreditation of Rehabilitation Facilities. MetroHealth is also accredited for full participation in Medicare and Medicaid.
- **Community Health Assessment** - MetroHealth took the lead in 1996 to initiate and participate in a health assessment of the people of Cleveland. The development of this knowledge will better enable all health care providers to focus their efforts and evaluate their results.
- **OB/GYN** - MetroHealth is internationally recognized in the areas of maternal/fetal medicine and exercise therapy during pregnancy.
- **Cancer Care** - MetroHealth's oncology service, along with two other Cleveland organizations, is a major clinical component of the National Cancer Institute-sponsored academic cancer center.